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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,228	11/05/2003	Michael R. Slater	341.030US1	8004
21186 7590 04/05/2007 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/702,228	SLATER ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 13-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-67 are pending in the case.

Receipt of the Information Disclosure Statement on 1/22/07 is acknowledged.

Claims 13-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/2/06.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bilcock et al. (J. Biol. Chem. 274, 51, 36379-36386, 1999) (cited by applicants).

Bilcock et al. disclose a vector comprising a recognition site for Sgfl, which generates a 3'TA overhang, which is 5' to a recognition site for a second restriction enzyme which generates blunt ends, i.e. an enzyme such as Sall, EcoRV, or Ball, HindIII, which may yield blunt ends (see Fig. 1, pDB8 or pDB7). The vector would,

when cut digested with the first and second restriction enzymes and ligated to a DNA fragment comprising an open reading frame flanked by the ends recited in claim 1, yield a recombinant vector comprising the open reading frame. It is noted that the second phrase, i.e. that reciting the DNA fragment, does not limit or change the claimed subject matter, which is the vector comprising the first and second restriction site.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 10/20/06. Applicant's arguments filed 1/22/07 have been considered but have not been found convincing.

Applicant has argued that the vectors disclosed in Bilcock et al." i.e. pAT153, pDB7, and pDB8 in Figure 1, if cleaved with a restriction enzyme that generates a 3' TA overhang (Sgfl in pAT153, pDB7, and pDB8) and a restriction enzyme which generates blunt ends (SrlI in pAT153, pDB7, and pDB8), would not yield a vector backbone where the end generated by Sgfl could be ligated 5' to an open reading frame, because the restriction enzyme which generates blunt ends in pAT153, pDB7, and pDB8 is 5' to the site for Sgfl". However, it is maintained that the reference is properly cited, since the restriction enzyme that generates a 3'TA overhang, i.e. Sgfl in pDB7 and pDB8, generates the same 3'TA overhang on each side or strand of the restriction site, and therefore applicant's statement that "the restriction enzyme which generates blunt ends in pAT153, pDB7, and pDB8 is 5' to the site for Sgfl" is not agreed with. Since the vector is a plasmid and is circular, and the Sgfl cut site is symmetrical, the blunt end cut site is 5' of the Sgfl site. Applicant's further arguments at page are drawn to vectors,

which were not cited in the previous action. Therefore, applicant's arguments are not found convincing and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

This is a new rejection necessitated by applicant's amendments to the claims.

Claims 1 and by dependence claims 2-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the invention as now claimed: "wherein the site in the recombinant vector formed by ligation of the 3' TA overhang and the end generated by Sgfl is 5' to the open reading frame, and wherein if the vector backbone has an open reading frame that is 5' to the site and is in frame with the open reading frame 3' to the site, the vector backbone includes a promoter that is operably linked to the open reading frame which is 5' to the site".

This is a new matter rejection. The specification does not provide sufficient blazemarks nor direction for the instant methods encompassing the above-mentioned

limitations, as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for the reasons made of record in the previous Office action, mailed 10/20/06.

To recapitulate:

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claims 10-12 are drawn to a vector comprising a recognition site that generates a 3'TA overhang which is 5' to a recognition site for a second enzyme that generates blunt ends, which vector when digested with said enzymes and ligated to a DNA fragment comprising an open reading frame flanked by an end generated by Sgfl and an end generated by a third restriction enzyme that has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends yields a recombinant vector

comprising the open reading frame, and wherein the ligation generates particular sequences recited in claims 10-12. Claims 10-12 are genus claims in terms of vectors which when cut with restriction enzymes which generate a –TA end and a blunt end, and when ligated to fragments having ends generated by Sgfl and an enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, yields particular sequences at the ligation point. The

The claims encompass a broad class of vectors having any restriction enzyme sites that meet certain characteristics regarding frequency of occurrence and the ends produced after restriction, and the resulting sequences after ligation to DNA fragments, and many unspecified and unknown restriction sites and enzymes may be encompassed which are not described. While the specification provides general information on the nature of the sites, which may be utilized, there is no disclosure of the precise structure of a representative number of restriction sites that are encompassed by the claim. One of skill in the art cannot envision all the vectors having restriction sites, which will yield the claimed vector based on the teachings of the specification. Therefore, the specification does not describe the claimed vectors having particular restriction enzyme sites in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Applicant's arguments filed 1/22/07 have been considered but have not been found convincing.

Applicant has argued that stop codons are known, as well as restriction enzymes that leave 3' TA ends, blunt ends, and that cut infrequently in cDNAs. It is acknowledged that such enzymes are known in the art. However, it is maintained that the claims are drawn to vectors which when cut with restriction enzymes which generate a –TA end and a blunt end, and when ligated to fragments having ends generated by Sgfl and an enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, yields particular sequences at the ligation point. There is insufficient written description of such enzymes and vectors that will result when ligated to fragments, will result in the recited particular sequences. Therefore, the rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
3/29/07


NANCY VOGEL
PRIMARY EXAMINER